United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

TAKE2 TECHNOLOGIES LIMITED, et al.,

Plaintiffs,

v.

PACIFIC BIOSCIENCES OF CALIFORNIA INC,

Defendant.

Case No. 23-cv-04166-EJD

ORDER DENYING DEFENDANT'S MOTION TO DISMISS

Re: ECF Nos. 13, 14

Plaintiffs Take2 Technologies Limited ("Take2") and The Chinese University of Hong Kong ("CUHK" and, with Take2, "Plaintiffs") bring this action against Defendant Pacific BioSciences of California, Inc. ("PacBio" or "Defendant") for infringement of United States Patent No. 11,091,794 (the "'794 Patent" or the "Patent-in-Suit") in violation of 35 U.S.C. § 271. *See* Compl., ECF No. 2. Now pending before the Court is Defendant's motion to dismiss Plaintiffs' Complaint (the "Motion") pursuant to Federal Rule of Civil Procedure 12(b)(6), in which Defendant argues that the '794 Patent is ineligible for patenting under 35 U.S.C. § 101. *See* Mot., ECF No. 13; Mem. P. & A. ("MPA"), ECF No. 14. The Court heard oral argument on the Motion on February 22, 2024. *See* ECF No. 98. Having reviewed the parties' written and oral arguments and the governing law, the Court DENIES the Motion for the reasons discussed below.[1]

[1] The Complaint was filed under seal, *see* Compl., but the parties filed their briefs regarding the Motion on the public docket. All allegations and arguments discussed in this Order are available in publicly filed documents.

I. BACKGROUND

A. Factual Allegations

The Patent-in-Suit is titled "Determination of Base Modifications of Nucleic Acids." *See* Decl. of Kathryn Leicht in Supp. of Mot. ("Leicht Decl."), Exh. 1 ("'794 Patent"), at [54] (filed Aug. 17, 2020), ECF No. 15-1.[2] Plaintiffs allege that the invention disclosed in the Patent-in-Suit improves gene sequencing (also called DNA sequencing) technology with respect to detecting information about modifications to the four nucleotides—adenine (A), cytosine (C), guanine (G), and thymine (T)—that form the structural basis for DNA sequences. *See* Opp'n 2 (citing Compl. ¶ 11), ECF No. 31; *see also* Compl. ¶ 11. As the Patent-in-Suit explains, nucleotide modifications such as methylation—the addition of a methyl group to a nucleotide base—play an important role in gene expression in mammals, and many human diseases have been associated with DNA methylation aberrations. *See* '794 Patent, col. 1 ll. 39–65. Accordingly, the accurate measurement of base modifications could have numerous clinical implications. *See id.* at col. 2 ll. 3–5.

The Patent-in-Suit describes the prior procedures used to measure base modifications, including chemically treating DNA samples with bisulfite prior to sequencing—and sometimes further subjecting the DNA to a polymerase chain reaction (PCR) amplification procedure—and explains that these approaches significantly degrade the majority of the treated DNA. *See id.* at col. 2 ll. 5–31. The Patent-in-Suit discloses that prior research efforts had attempted to achieve a commercially viable bisulfite-free determination of base modifications, but that no study had been able to determine modification with meaningful or practical accuracy. *See id.* at col. 17 ll. 7–10, col. 19 ll. 38–42. The inventors additionally note that the prior studies did not provide sufficient information to know whether their research methods would be "feasible to use . . . for genomewide methylomic analysis, especially for complex genomes such as human genomes, cancer genomes, or fetal genomes." '794 Patent, col. 19 ll. 46–50.

[2] The Court may consider the contents of the Patent-in-Suit without converting the instant Motion into a motion for summary judgment because the Patent-in-Suit forms the basis of Plaintiffs' claim and is thus incorporated by reference into the Complaint. *See United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)

By contrast—according to the Patent-in-Suit—the disclosed invention allows for direct detection of modifications without enzymatic or chemical conversion of the sample DNA and without PCR amplification. *See id.* at col. 20 ll. 26–31. The disclosed methods therefore result in more accurate, practical, and convenient detection of base modifications because, for example, they (1) avoid degradation of DNA samples so that more modification information is available for detection; (2) avoid the problem of certain enzymatic or chemical conversions being incompatible with certain types of modifications; (3) avoid the potential of PCR amplification failing to transfer base modification information to the PCR products; and (4) enable the sequencing of DNA strands, unlike PCR amplification. *See id.* at col. 20 ll. 29–41.

The Patent-in-Suit recites one independent claim (Claim 1) and 18 dependent claims (Claims 2–19). *See id.* at col. 115 l. 38–col. 118 l. 48. Plaintiffs allege that Defendant infringed "at least claim 1." *See* Compl. ¶ 36; *see also* Opp'n 10 (citing same). Claim 1 recites the following method:

> 1. A method for detecting a modification of a nucleotide in a nucleic acid molecule, the method comprising:
>
> a. receiving data acquired by measuring pulses in an optical signal corresponding to nucleotides sequenced in a sample nucleic acid molecule and obtaining, from the data, values for the following properties:
> for each nucleotide:
> an identity of the nucleotide,
> a position of the nucleotide within the sample nucleic acid molecule,
> a width of the pulse corresponding to the nucleotide, and
> an interpulse duration representing a time between the pulse corresponding to the nucleotide and a pulse corresponding to a neighboring nucleotide;
>
> b. creating an input data structure, the input data structure comprising a window of the nucleotides sequenced in the sample nucleic acid molecule, wherein the input data structure includes, for each nucleotide within the window, the properties:
> the identity of the nucleotide,
> a position of the nucleotide with respect to a target position within the window,
> the width of the pulse corresponding to the nucleotide, and
> the interpulse duration;

> c. inputting the input data structure into a model, the model trained by:
> receiving a first plurality of first data structures, each first data structure of the first plurality of data structures corresponding to a respective window of nucleotides sequenced in a respective nucleic acid molecule of a plurality of first nucleic acid molecules, wherein each of the first nucleic acid molecules is sequenced by measuring pulses in the optical signal corresponding to the nucleotides, wherein the modification has a known first state in a nucleotide at a target position in each window of each first nucleic acid molecule, each first data structure comprising values for the same properties as the input data structure,
> storing a plurality of first training samples, each including one of the first plurality of first data structures and a first label indicating the first state of the nucleotide at the target position, and
> optimizing, using the plurality of first training samples, parameters of the model based on outputs of the model matching or not matching corresponding labels of the first labels when the first plurality of first data structures is input to the model, wherein an output of the model specifies whether the nucleotide at the target position in the respective window has the modification,
> d. determining, using the model, whether the modification is present in a nucleotide at the target position within the window in the input data structure.

'794 Patent, col. 115 l. 38–col. 116 l. 61. In brief, Claim 1 of the Patent-in-Suit recites a method for using a neural network model to detect base modifications by (1) using a DNA sequencing system[3] on a DNA molecule to receive, for each nucleotide in the DNA molecule, four data inputs: (a) nucleotide identity, (b) nucleotide position within sample DNA molecule, (c) width of optical signal's pulse at the nucleotide (pulse width, or "PW"), and (d) interpulse duration ("IPD"), *i.e.*, time between pulse at present nucleotide and pulse at neighboring nucleotide; (2) focusing on a window—presumably a subset—of the sequenced DNA and creating an input data structure for the model that includes the above four data properties for each nucleotide within the window (except that the second property of nucleotide position refers to each nucleotide's position relative to a chosen target nucleotide position within the window, rather than the position within the entire

[3] The Patent-in-Suit notes that Defendant has commercialized a single molecule, real-time sequencing system ("SMRT"). *See* '794 Patent, col. 2 ll. 58–61.

molecule); (3) inputting the created data structure into the invented model; and (4) using the model to determine the presence of a modification at the chosen target nucleotide position within the window. *See id.* Plaintiffs allege that they invented the neural network model recited at the final two steps of Claim 1. *See id.*; *see also* Compl. ¶ 13; Opp'n 7 (citing same).

B. Procedural History

Plaintiffs filed the operative Complaint in the United States District Court for the District of Delaware on December 14, 2022. *See* Compl. Defendant filed the instant Motion in the District of Delaware on February 14, 2023, and the Motion has been fully briefed since April 13, 2023. *See* Mot.; MPA; Opp'n; Reply, ECF No. 36.

While this action was still pending in Delaware, the district court issued an oral order noting that the Federal Circuit had recently issued a decision in *Hantz Software, LLC v. Sage Intacct, Inc.*, No. 2022-1390, 2023 WL 2569956 (Fed. Cir. Mar. 20, 2023); that the *Hantz* decision found it inappropriate to address the patent eligibility of claims not asserted in the operative pleading at the motion to dismiss stage; and that Defendant's Motion focuses on Claim 1 "but also attempts to reach the other 18 claims of the patent." *See* ECF No. 48. The court ordered Plaintiffs to file a letter advising the court as to whether Claim 1 is the only claim likely to be litigated in this action. *See id.* Accordingly, on May 31, 2023, Plaintiffs filed a letter stating that they expected to assert at least Claims 1–3, 6–8, 10–16, and 18–19. *See* ECF No. 49.

On August 2, 2023, the district court in Delaware granted Defendant's motion to transfer venue to the Northern District of California, *see* ECF No. 61, and the action was transferred on August 16, 2023, *see* ECF No. 63. The Court set a hearing on the Motion for October 26, 2023. *See* ECF No. 70. However, prior to the hearing on the Motion, Plaintiffs filed a motion to disqualify Defendant's in-house legal department from representing Defendant in this action, arguing that one in-house counsel had previously represented Take2 in pre-litigation matters directly concerning this action. *See* ECF No. 75. Following oral argument, the Court granted in part the motion to disqualify, and subsequently modified that order. *See* ECF Nos. 90, 92, 95. The Court continued the hearing on the instant Motion during the pendency of the disqualification

motion, and, following a stipulated request from the parties, heard oral argument on the Motion on February 22, 2024. *See* ECF Nos. 86, 89, 93, 97, 98.

II. LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(6)

Under Federal Rule of Civil Procedure 12(b)(6), a court must dismiss a complaint that fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the plaintiff pleads facts permitting the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged," although the allegations must show "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

In evaluating a Rule 12(b)(6) motion, the court must accept as true all well-pleaded factual allegations and construe them in the light most favorable to the plaintiff. *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011). But the court need not "accept as true allegations that contradict matters properly subject to judicial notice" or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (internal quotation marks and citations omitted).

"[P]atent eligibility can be determined at the Rule 12(b)(6) stage." *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) (citations omitted); *see also, e.g., Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1036, 1312 (Fed. Cir. 2019). To succeed on a Rule 12(b)(6) motion based on patent ineligibility, the movant must show that "there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law." *Aatrix Software*, 882 F.3d at 1125.

B. Patent Eligibility

"Patent eligibility is governed by 35 U.S.C. § 101, which provides that 'whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

requirements of this title.'" *Sanderling Mgmt. Ltd. V. Snap Inc.*, 65 F.4th 698, 702 (Fed. Cir. 2023) (alterations omitted) (quoting 35 U.S.C. § 101)). Accordingly, "[a] § 101 analysis begins by identifying whether an invention fits within one of the four statutorily provided categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter." *Aatrix Software*, 882 F.3d at 1125 (quoting *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 713–14 (Fed. Cir. 2014)). However, the Supreme Court has recognized that these broad categories of patent-eligible materials contain an implicit exception, such that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (internal quotation marks and citation omitted). In applying this exception, courts "must distinguish between patents that claim the building blocks of human ingenuity and those that integrate the building blocks into something more." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (internal quotations and citation omitted).

In *Alice*, the Supreme Court established a two-step framework to determine whether a claim falls within the "abstract idea" exception. First, the court must "determine whether the claims at issue are directed to a patent-ineligible concept." *Alice*, 573 U.S. at 217. This inquiry is a "meaningful one" and "cannot simply ask whether the claims involve a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions involves a law of nature and/or natural phenomenon." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016). "Rather, the . . . inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Id.* (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)).

Second, if the claims are directed to patent-ineligible subject matter, the court must "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 573 U.S. at 217 (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 78 (2012)). For example, "a new combination of steps in a process may be

patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). "The second step of the *Alice* test is satisfied when the claim limitations 'involve more than performance of "well-understood, routine, [and] conventional activities previously known to the industry."'" *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (quoting *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1347–48 (Fed. Cir. 2014)). Whether the elements of a claim or the claimed combination are well-understood, routine, and conventional activities "is a question of fact" that—if subject to a genuine dispute—"cannot be answered adversely to the patentee based on the sources properly considered on a motion to dismiss." *Aatrix Software*, 882 F.3d at 1128; *see also Berkheimer*, 881 F.3d at 1369 ("While patent eligibility is . . . a question of law, . . . [w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.").

III. DISCUSSION

Defendant argues that this action must be dismissed because the Patent-in-Suit claims ineligible subject matter under § 101. *See* MPA 1. Specifically, Defendant argues that application of the two-step *Alice* framework establishes (1) that the claims in the Patent-in-Suit are "directed to the abstract idea of using a statistical model to predict what modified bases are present in a nucleic acid strand such as DNA," *id.* at 4, and (2) that Plaintiff's purported inventive advance is merely "the abstract idea of adding new parameters to a statistical model [that] cannot as a matter of law provide the 'something more' for step [two]" of the *Alice* test, *id.* at 7 (citing *BSG Tech LLC v. Buyseasons, Inc.*, 899 F. 3d 1281 (Fed. Cir. 2018)). Plaintiffs oppose both arguments, *see* Opp'n 11–20, and additionally assert that the Motion must be denied because (1) there are disputed issues of fact in the second step of the *Alice* analysis, *see id.* at 5–8; (2) the Motion is underdeveloped because the Court should not evaluate eligibility of the Patent-in-Suit, which concerns a technically sophisticated subject, without the benefit of "an adequate expert-aided technical understanding of the cited references," *id.* at 8–9; and (3) the Motion does not address the dependent claims and should be denied at least with respect to those claims, *see id.* at 10–11.

The Court notes at the outset that the argument that the Court should not evaluate the merits of the Motion due to the highly technical nature of the subject matter must be rejected—not because the Court disputes Plaintiffs' characterization of the Patent-in-Suit, but rather because the evaluation by courts of the legal sufficiency of patent infringement claims is simply part of the judicial system, regardless of the complexity of the underlying subject matter.

The Court now turns to the parties' substantive arguments regarding patent eligibility under § 101. As noted above, *see supra*, at Part II(B), "[a] § 101 analysis begins by identifying whether an invention fits within one of the four statutorily provided categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter." *Aatrix Software*, 882 F.3d at 1125 (citation omitted). It appears that the parties implicitly agree that the most relevant category here is the "process" group. *See* Opp'n 18 (stating that claimed invention is a "specific implementation . . . [that] amounts to improving an existing technological process") (internal alterations, quotation marks, and citation omitted); Reply 7 (arguing that claimed invention did not improve DNA sequencing process). However, Defendant argues that the Patent-in-Suit discloses an abstract idea that falls into the long-recognized "implicit exception," *Alice*, 573 U.S. at 216 (citation omitted), to the statutory eligibility categories. *See* MPA 4. The Court thus turns to the two-step analysis under *Alice*. It will address Plaintiffs' argument about disputed issues of fact within the *Alice* analysis—rather than as a threshold issue, as suggested by Plaintiffs, *see* Opp'n 5–8—and will lastly address the question of dependent claims.

A. *Alice* Step One: Whether the Patent-in-Suit is Directed to an Abstract Idea

Defendant contends that "[t]he claims in the '794 Patent are directed to the abstract idea of using a statistical model to predict what modified bases are present in a nucleic acid strand such as DNA." MPA 4. Plaintiffs respond that the Patent-in-Suit's claims "are not directed to an abstract idea but to using a specific technique in a specific way in the sequencing context to measure previously unmeasurable properties." Opp'n 11.

"Whether or not an idea is abstract is generally determined by 'comparing claims at issue to those claims already found to be directed to an abstract idea in previous cases.'" *Samsung*

Elecs. Co. Ltd. v. Blaze Mobile, Inc., 673 F. Supp. 3d 1066, 1075 (N.D. Cal. 2023) (alterations omitted) (quoting *Enfish*, 822 F.3d at 1334). The Court reviews the most analogous cases cited by the parties before comparing the present claims to the claims evaluated in those cases.

1. Review of Prior Cases

Defendant points the Court to *In re Board of Trustees of Leland Stanford Junior* ("*In re Stanford*"), 991 F.3d 1245 (Fed. Cir. 2021), and *Wisk Aero LLC v. Archer Aviation Inc.*, No. 21-cv-02450, 2022 WL 1157489 (N.D. Cal. Apr. 19, 2022), while Plaintiffs urge the Court to follow *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), and *CardioNet, LLC v. Infobionic, Inc.*, 955 F.3d 1358 (Fed. Cir. 2020). *See* MPA 4–7; Opp'n 12–14.[4] The Court provides a brief summary of each of these cases.

In *In re Stanford*, the Federal Circuit affirmed the Patent Trial and Appeal Board's ("PTAB") decision rejecting the claims in the appellant's patent application (the "'982 Application"). *See* 991 F.3d at 1246. The'982 Application was "directed to methods for inferring haplotype phase in a collection of unrelated individuals," where a "haplotype phase acts as an indication of the parent from whom a gene has been inherited. *Id.* at 1247. There existed prior art methods to infer haplotype phase using statistics-based algorithms; these methods included models titled PHASE, fastPHASE, and Beagle, all of which involved using a known statistical tool—a hidden Markov model, or "HMM"—used in "various applications to make probabilistic determinations of latent variables." *Id.* The '982 Application disclosed an embodiment in which a statistical model—allegedly a "modified version of the preexisting PHASE model [that] operate[d] more efficiently and accurately than the PHASE model"—predicted haplotype phase. *Id.* The Federal Circuit found the '982 Application's claims were "directed to the use of mathematical calculations and statistical modeling," noting that the method used mathematical techniques including "building a data structure describing an HMM" and then repeatedly recomputing the HMM's parameters following random modifications. *In re Stanford*, 991 F.3d at 1250. The Court

[4] The Court does not suggest that the parties cited only these cases, but these four cases are at the heart of the parties' written and oral arguments.

further held that other steps recited in the relevant claim—"receiving genotype data, imputing an initial haplotype phase, extracting the final predicted haplotype phase from the data structure, and storing it in a computer memory"—were generic steps to make calculations with a regular computer, so that they did not change the character of the claim to a practical application. *Id.*

In *Wisk Aero*, the district court found a disclosed "method of controlling flight of an aircraft" to be patent ineligible. *See Wisk Aero*, 2022 WL 1157489, at *4 (quoting U.S. Patent No. 10,370,099 (the "'099 Patent")). The method consisted of "receiving a set of inputs" and "computing an optimal mix of actuators and associated . . . parameters to achieve" the desired result. *See id.* (quoting '099 Patent). The claimed advance over the prior art was that the computational step included "the minimization of a weighted set of costs, including costs of errors." *Id.* The court held the computation at issue to be a mathematical technique or method, although it emphasized that its analysis was not based on the mere involvement of some computation, as "[a]ny number of claims involving computing can be valid." *Id.* at *4 & n.1. The court further noted that the supposedly "novel solution of including error as a weighted cost in a . . . function" underlined the conclusion that the claimed advance was merely the inclusion of "a new mathematical step" in the existing computational model. *See id.* at *5. Additionally, the court distinguished the '099 Patent from that considered in *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), where the claimed advance involved not merely an underlying mathematical technique, but rather the combination of an equation with the disclosed placement of sensors to receive signal data from which the orientation of an object could be determined. *See Wisk Aero*, 2022 WL 1157489, at *6 (citing *Thales*, 850 F.3d at 1345–46, 1348).

The claims in *Thales* recited the mounting of inertial sensors on both a tracked object and a moving platform, and the subsequent receipt of data from those two sensors and calculation of the orientation of the tracked object relative to the moving platform. *See Thales*, 850 F.3d at 1348. The prior "conventional solutions for tracking inertial motion of an object on a moving platform," which also included two inertial sensors, a tracked object, and a moving platform, were "flawed" and less accurate than the disclosed invention because they measured inertial changes with respect

to the earth, rather than in relation to the frame of the moving platform. *Id.* at 1345. The Federal Circuit found the claims "not merely directed to the abstract idea of using 'mathematical equations for determining the relative position of a moving object to a moving reference frame,'" but rather to "systems and methods that use inertial sensors in a nonconventional manner to reduce errors in measuring the relative position and orientation." *Id.* at 1348–49. As the court noted, "[t]hat a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction." *Id.* at 1349.

Lastly, in *CardioNet, LLC v. InfoBionic, Inc*, 955 F.3d 1358 (Fed. Cir. 2020), the Federal Circuit reversed the district court's decision and held that a patentee's disclosed claims were "directed to a patent-eligible improvement to cardiac monitoring technology and . . . not to an abstract idea," where the claimed invention was a cardiac monitoring device whose "systems and techniques" detected and distinguished specific forms of cardiac arrythmia—atrial fibrillation or atrial flutter—by "determin[ing] the variability in heart rate" through the measurement and analysis of the timing between peaks of electrocardiogram signals. *See CardioNet*, 955 F.3d at 1362. The first independent claim recited a device detecting and reporting the presence of atrial fibrillation or atrial flutter by detecting heart beat information and analyzing the data using "relevance determination logic." *See id.* at 1364–65. The circuit court noted that there was no suggestion in the patent's written description "that doctors were 'previously employing' the techniques performed on the claimed device," so that "[n]othing in the record . . . suggest[ed] that the claims merely computerize[d] pre-existing techniques for diagnosing" the cardiac arrhythmias. *Id.* at 1370. The court held that the district court's generalization of the asserted claims "as being directed to collecting, analyzing, and reporting data" was inconsistent with the Federal Circuit's "instruction that courts 'be careful to avoid oversimplifying the claims' by looking at them generally and failing to account for the specific requirements of the claims." *Id.* at 1371 (quoting *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016)).

2. Review of Patent-in-Suit

The Patent-in-Suit's specification explains that prior successful methods for detecting the

presence of base modifications involved either the application of bisulfite to the DNA sample or the use of multiple steps of enzymatic and chemical reactions. *See* '794 Patent, col. 17 ll. 7–15. The specification then discusses studies that have used IPD-based algorithms to detect various base modifications in a DNA sequence, explaining that "these previous attempts of utilizing IPD only or with combination of sequence information in the neighboring nucleotides for grouping data were not able to determine the base modification of [the important base modification] 5-methylcytosine with meaningful or practical accuracy." *Id.* at col. 19 ll. 38–42; *see also id.* at col. 18 l. 66–col. 19 l. 2. "In contrast to previous studies," embodiments of the disclosed method "are based on measuring and utilizing IPD, PW, and sequence context for every base within the measurement window" because the patentees "reasoned that if [one] use[d] a combination of multiple metrics . . . [one] might be able to achieve the accurate measurement of base modifications . . . at single-base resolution." *Id.* at col. 19 ll. 51–60. As summarized in the specification's conclusion, the patentees "developed an efficient approach to predict the base modification . . . levels of nucleic acids at single-base resolution," which involved "concurrently capturing [measurements for bases] surrounding the base being interrogated" and which, "[c]ompared with previous methods [that] used IPD only, . . . much improved the resolution and accuracy in methylation analysis." '794 Patent, col. 109 ll. 10–20.

The specification therefore indicates that the claimed advance was the patentees' deduction that using specific metrics available from a DNA sequencing read—including but not limited to IPD–could lead to a more accurate prediction of base modification, and the creation of the model that could make the prediction with the deduced inputs. Accordingly, reading Claim 1 of the Patent-in-Suit as a cohesive whole with the specification, the Court finds that it is directed to retrieving specific data inputs from a sequencing read of a nucleic acid molecule, creating a data structure based on the data, and inputting the data structure into a model trained to predict the presence of a nucleotide base modification based on the relevant inputs, and thereby determining the existence of the modification. *See* '794 Patent, col. 115 l. 38–col. 116 l. 61. This method is similar to that evaluated by the district court in *Wisk Aero*—where the claimed advance was the

addition of a cost minimization factor to a mathematical analysis—where the court reasoned that "factoring in specific inputs" into an algorithm was not patentable. *Wisk Aero*, 2022 WL 1157489, at *4–5. As noted in the *Wisk Aero* decision, the Federal Circuit has held that "selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis" is an abstract idea. *Id.* at *5 (quoting *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018)). Likewise, in *In re Stanford*, the Federal Circuit found abstract claims reciting a method to predict haplotype phase, where the steps included "building a data structure," "receiving genotype data, imputing an initial haplotype phase, [and] extracting the final predicted haplotype phase from the data structure." *In re Stanford*, 991 F.3d at 1250. Like the claimed method in *In re Stanford*, the method recited in Claim 1 of the Patent-in-Suit involves steps to receive specific input data, build a data structure, input the data to a model, and extract the final prediction. *See* '794 Patent, col. 115 l. 38–col. 116 l. 61. Such a claim is "directed to the use of mathematical calculations and statistical modeling," and is thus abstract. *In re Stanford*, 991 F.3d at 1250 (citations omitted).

The cases cited by Plaintiffs are materially distinguishable. *Thales* involved not only a new understanding of different inputs to use in a calculation, but—unlike the method claimed here—also a change in the configuration of a physical system in order to obtain those required inputs. *See Thales*, 850 F.3d at 1345. In *CardioNet*, the Federal Circuit explained that the district court's error had been to assume that the claims automated known techniques, where in fact there was "no suggestion in the [patent's] written description that doctors were 'previously employing' the techniques performed on the claimed device." *CardioNet*, 955 F.3d at 1370. Here, by contrast, the Patent-in-Suit's specification describes that other researchers were detecting base modifications—if less accurately, especially with respect to the specific 5-methylcytosine modification on which Plaintiffs focused their efforts—by using optical pulse data obtained from a sequencing read and inputting the data into an algorithm. *See* '794 Patent, cols. 17–19. The Court therefore cannot say that Claim 1 of the Patent-in-Suit is directed to a technological improvement in the means or method of detecting base modifications; rather, the claim is directed to an

algorithmic improvement within the field of research on using optical pulse data to detect base modifications.

For these reasons, the Court finds that Claim 1 of the '794 Patent is directed to an abstract idea, and proceeds to step two of the *Alice* analysis.

B. *Alice* Step Two: Whether the Patent-in-Suit Adds an Inventive Concept to the Abstract Idea

Because the Court finds that Claim 1 of the Patent-in-Suit is directed to patent-ineligible subject matter, *i.e.*, an abstract idea, the Court must engage in what the Supreme Court has described as a search for an "inventive concept": an element or combination of elements that "in practice amounts to significantly more than a patent upon the [abstract idea] itself." *Mayo*, 566 U.S. at 72–73 (citation omitted). Defendant argues that any suggestion that Plaintiffs' claimed invention was "not well-understood, routine, or conventional" fails as a matter of law because the purported advance was merely the selection and use of new parameters in a data structure and model, and the new parameters were properties that were well-known, if not previously used in combination. *See* MPA 7–11. Plaintiffs argue that (1) whether their claimed advance was well-understood, routine, or convention is, based on the Complaint's allegations, a question of fact that cannot be decided on a motion to dismiss, *see* Opp'n 5–8, and (2) the Patent-in-Suit does not disclose merely the addition of new parameters to a model, but rather the "use of an unconventional model in a new technical context . . . [that] improves the operation of nucleic-acid sequencers," Opp'n 16; *see also id.* at 16–20.

Defendant's arguments as to the non-inventive nature of the method recited in Claim 1 all focus on the selection and addition of new parameters to a statistical model, which—as Defendant correctly notes—is itself the abstract idea discussed in *Alice* step one and therefore cannot alone survive *Alice* step two. *See* MPA 7–11; *see also BSG Tech*, 899 F.3d at 1290 ("It has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept."). However, Claim 1 also recites, for example, the use of a "window of the nucleotides

sequenced" and the placement of a "nucleotide at the target position in the respective window." *See* '794 Patent, col. 115 l. 54; *id.* at col. 116 ll. 56–57; *see also* Opp'n 3, 7 (citing Compl. ¶ 13), 9. Defendant does not discuss this aspect of the claimed method. *See generally* MPA; Reply. Further, as Plaintiffs note, the Complaint makes several specific allegations regarding the industry reaction to Plaintiffs' claimed invention as an unconventional concept. *See* Opp'n 7 (citing Compl. ¶¶ 13–30). For example, the Complaint alleges that a scientific journal published a research article regarding the technique, *see* Compl. ¶ 14, and that Defendant itself described the claimed invention as a new development, *see id.* ¶ 17; *see also* MPA 10 (citing Compl. ¶ 65).

Accepting these allegations as true, as it must in evaluating a motion to dismiss, and in light of the lack of argument or further information about the conventionality of the sequence window recited in Claim 1, the Court cannot hold as a matter of law that the Patent-in-Suit does not disclose an inventive concept for the purposes of *Alice* step two. *See Cellspin*, 927 F.3d at 1318 ("[P]atentees who adequately allege their claims contain inventive concepts survive a § 101 eligibility analysis under Rule 12(b)(6)."") (quoting *Aatrix Software*, 882 F.3d at 1126–27); *see also, e.g., BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) ("[A]n inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces."). And although Defendant argues that its statements were not related to the Patent-in-Suit, *see* MPA 10, and further attaches four research papers in support of its argument that the Patent-in-Suit expressed no unconventional concept, *see id.* at 8–9, these arguments raise questions of fact that cannot be decided at this stage, and certainly not against Plaintiffs. *See Aatrix Software*, 882 F.3d at 1128 ("Whether the claim elements or the claimed combination are well-understood, routine, conventional is a question of fact.").

Accordingly, the Court finds that Defendant has not carried its burden of showing that "there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law." *Id.* at 1125. The Court will therefore deny Defendant's motion as to Claim 1.

C. Dependent Claims

Defendant appears to have understood the Complaint to assert only Claim 1 of the Patent-

in-Suit. *See* MPA 11 ("Even if Plaintiffs had asserted the dependent claims, that would not save their case. . . . Nor would they be properly asserted – which is presumably why they are not included in the complaint."). However, as clarified by Plaintiffs following the Delaware district court's order, *see supra*, at Part I(B), and as noted in Plaintiffs' opposition to the Motion, *see* Opp'n 10–11, the Complaint asserts that Defendant infringed "at least claim 1" of the Patent-in-Suit, and Plaintiffs intend to assert several of the dependent claims. Defendant did not address the dependent claims in its reply in support of the Motion. *See* Reply. Because the Motion did not address the asserted dependent claims, the Court does not evaluate them.

IV. CONCLUSION

For the foregoing reasons, the Court hereby ORDERS as follows:

1. The Court finds Claim 1 of the Patent-in-Suit to be directed to an abstract idea;
2. The Court finds that Defendant has not shown as a matter of law that Claim 1 of the Patent-in-Suit lacks an inventive concept sufficient under *Alice* step two; and accordingly,
3. Defendant's Motion is DENIED.
4. Within 10 days of the entry of this order, the parties shall meet and confer and submit a joint proposed scheduling order for the remainder of this action. The parties shall additionally inform the Court as to whether there is a need for any portion of the Complaint to remain under seal.

IT IS SO ORDERED.

Dated: March 25, 2024

EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California